



Wyeth Vaccines

One Blue Hill Plaza, BH 21-125
Pearl River, NY 10965-8668

Jack D. Love, Ph.D.

Assistant Vice President
Global Regulatory Affairs -Vaccines

June 30, 2006

Dr Cindy Dougherty
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

COL John D. Grabenstein, RPh, Ph.D.
Deputy Director for Military Vaccines
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258

Re: STN 101106/5078 – Smallpox Vaccine, Dryvax®
Extension of Dating

Dear Dr.Dougherty and COL Grabenstein:

This is to inform you that Wyeth received approval on June 30, 2006 for BLA Supplement 101106/5078 for extension of dating of the following lots:

Packaged Lot (Fill Lot) 4018142(302701), 4018143(303001), 4018144 (302001), 4020077 (302301), 4020076 (313701), 4030020 (313601), 4020071 (317501), 4020072 (321401), 4020074 (321301), 4020075 (317602), and 4030014 (302501) of Smallpox Vaccine Dryvax® through December, 2006.

Packaged Lot (Fill Lot) 4030013 (317401) of Smallpox Vaccine Dryvax® through October, 2006.

Please note that the storage period of the vaccine **after reconstitution with diluent** continues to be 90 days.

Sincerely yours,

Jack D. Love, Ph.D.

jl:be

Wyeth

cc: J.Becher (ORISE Fellow)
Hye-Joo Kim (CDC)
D. Foley (AMDG Consulting)
D. Staten (CBER)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Submission Tracking Number (STN): BLS 101106/5078

- Jack D. Love, Ph.D.
Wyeth Pharmaceuticals, Inc.
One Blue Hill Plaza, BH 21-125
Pearl River, NY 10965-8668

JUN 30 2006

Dear Dr. Love:

We have received your February 10, 2006, Supplement to your Biologics License Application for Smallpox Vaccine, Dryvax[®], to include an extension of dating period for lots 302301, 313601, 313701, 302501, 317501, 317602, 321301, and 321401 of Dryvax[®] until December 31, 2006. Additionally, lot 317401 is extended until October 31, 2006.

This acknowledgment recognizes that your submission is in the form of a **"Supplement-Changes Being Effectuated"** as described under 21 CFR 601.12(f)(2). Continued use of the change is subject to final approval of this Supplement.

This Supplement has been reviewed under STN 101106/5078 and is approved effective this date

This information will be included in your License Application File.

Sincerely yours,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research